

REMARKS

Response to §103 Rejections of Claims 1, 3, 5, 13 and 16-19 Over Abe '911 and Shimada

In the September 14, 2007 Office Action, the Examiner finalized the previously raised rejections against claims 1, 3, 5, 13, and 16-19 under 35 U.S.C. §103(a) as allegedly obvious over the English Abstract of Japanese Patent Application No. 60-161911 to Abe et al. (hereinafter "**Abe '911**") in view of the English Abstract of Japanese Patent Application No. 59-013708 to Shimada et al. (hereinafter "**Shimada**").

Specifically, the Examiner asserted that **Abe '911** teaches use of a cosmetic composition containing cholesterol sulfate and/or its salt for improving dried skin, preventing aging of skin, providing skin with wetting characteristics, softness and luster by promoting the water retention function of skin, that **Shimada** teaches use of a cosmetic composition containing N-acetylamino sugars or their salts for providing smoothness, moist, springiness and luster to the skin, and that one of ordinary skill in the art would have found it obvious to combine the N-acetylamino sugars disclosed by **Shimada** into the cosmetic composition disclosed by **Abe '911** with the expectation of providing an ingredient suitable for moisturizing and improving the luster of skin. Further in support of the finding of obviousness, the Examiner cited *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), in which the Court of Customs and Patent Appeals held that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Applicants respectfully disagree with the Examiner's reasoning, for the following reasons:

Obviousness is a conclusion of law based upon factual determinations. It has been well established that when challenge is made on the ground that the claimed invention would have been obvious, all evidence relevant to the obvious-nonobvious issue must be considered. *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983). Because virtually all inventions are combinations of old elements known in the art, it is insufficient for the Examiner to merely establish that the separate elements of the invention existed in the prior art. The Examiner must consider what the prior art as a whole would have suggested to one skilled in the art. *Environmental Designs, Ltd. v. Union Oil Company of California*, 218 USPQ 865, 870 (Fed. Cir. 1983), citing *In re McLaughlin*, 170 USPQ 209, 212 (CCPA 1971). Specifically, the Examiner must view the beliefs of those in the field at the time.

Arkie Lures Inc. v. Gene Larew Tackle Inc., 43 USPQ2d 1294, 1297 (Fed. Cir. 1997). For example, evidence indicating that the combination of such separate elements was not viewed as technically feasible must be considered, since conventional wisdom teaching that a combination of known elements should not be made is itself evidence of non-obviousness. *Id.* Further, evidence of separate uses of such known elements for years, without combining their properties, also weighs on the side of unobviousness of the combination. *Id.*

In the present case, although the **Abe '911** and **Shimada** references separately disclose the cosmetic uses of cholesterol sulfate or a salt thereof and N-acetylamino sugars for improving skin appearance and feel, evidence also indicates that cholesterol sulfate and exfoliants such as N-acetylamino sugars are known to achieve their respective skin care benefits through opposite mechanisms or modes of action on the stratum corneum layer of the skin.

On one hand, **cholesterol sulfate is known to retard skin desquamation and increase stratum corneum layer thickness**, which in turn improves the water retention function of the skin and thereby provides skin with better wetting characteristics, softness and luster. Specifically, cholesterol sulfate has been shown to inhibit activities of certain enzymes (such as stratum corneum tryptic enzyme and chymotryptic enzyme) that have been implicated with desmosome breakdown and corneocyte desquamation, and it has long been known that excess cholesterol sulfate inhibits desquamation, and hydrolysis of cholesterol sulfate in the stratum corneum promotes corneocyte desquamation. See page 234-235 of the enclosed article by Madison entitled "Barrier Function of the Skin: 'La Raison d'Être' of the Epidermis," EPIDERMAL BARRIER FUNCTION, Vol. 121, No. 2, pp. 231-241 (Aug 2003), *citing* various scientific journal articles dated from 1994-2001.

On the other hand, **exfoliants such as N-acetylamino sugars are known to promote skin desquamation and reduce the stratum corneum layer thickness**. Specifically, exfoliants function to weaken or break the desmosome bonds that hold the corneocytes together and allow the cells to slough off from the skin surface, thereby resulting in a thinner stratum corneum layer that is more flexible and compact, reflects more light, and overall gives the skin a more youthful appearance. See pages 2 of the enclosed article by Diana L. Howard entitled "Skin Exfoliation" and published as "Sloughing Off" in LES NOUVELLES ESTHETIQUES in September 2003 (retrieved from http://www.dermalinstitute.com/New_IDI_Site/newIDHome/txtonly_NEW/skinexfoliation.htm on October 30, 2007).

The two articles cited hereinabove clearly reveal prior art knowledge of the opposite mechanisms of action through which cholesterol sulfate and exfoliants achieve their respective skin care benefits. The Examiner must consider the prior art as a whole, which includes not only the **Abe '911** and **Shimada** references disclosing skin care benefits achieved separately by cholesterol sulfate and N-acetylamino sugars, but also the knowledge of the opposite mechanisms of action by cholesterol sulfate and exfoliants, in determining obviousness or non-obviousness of the claimed invention of the present application.

The totality of the prior art disclosure as described hereinabove not only fails to teach or suggest, but actually leads away from, combination of cholesterol sulfate or a salt thereof and exfoliants such as N-acetylamino sugars. In other words, a person ordinarily skilled in the art, i.e., a person who would have been aware of the opposite mechanisms of action by cholesterol sulfate and exfoliants, would not be motivated toward, but would be motivated against, combining cholesterol sulfate or a salt thereof with exfoliants such as N-acetylamino sugars, due to the likelihood that the effects of these two ingredients would cancel each other out and thereby defeat the very purposes of the **Abe '911** and **Shimada** references.

Further, the skin care benefits of cholesterol sulfate or a salt thereof and N-acetylamino sugars have been known since 1984-1985, as indicated by the publication dates of the **Abe '911** and **Shimada** references. For over 15 years prior to the claimed invention of the present application, these two ingredients have been used separately in cosmetic compositions, with no evidence indicating that they have ever been combined in a single cosmetic composition. Such separate uses for years without combination prior to the present invention also support the non-obviousness of combining cholesterol sulfate or a salt thereof with N-acetylamino sugars.

Based on the foregoing, Applicants submit that contrary to the Examiner's assertions in the outstanding Office Action, it would **not** have been obvious for a person ordinarily skilled in the art to combine the cholesterol sulfate or a salt thereof disclosed by the **Abe '911** reference and the N-acetylamino sugars disclosed by the **Shimada** reference. Consequently, claims 1, 3, 5, 13, and 16-19 of the present application are patentable over **Abe '911** and **Shimada**.

Response to §103 Rejections of Claim 4 Over Abe '911, Shimada, and Abe '314

In the outstanding Office Action, the Examiner finalized the previous rejection of claim 4 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to

claims 1, 3, 5, 13, and 16-19 above, and further in view of Japanese Patent Application Publication No. 05-051314 to Abe et al. (hereinafter “**Abe ‘314**”).

Claim 4 depends directly from claim 3, which in turn depends from claim 1. Therefore, claim 4 incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof and an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe ‘911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe ‘911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant. **Abe ‘314** was filed after **Abe ‘911** by the same applicant, i.e., Kanebo Ltd. Specifically, **Abe ‘314** discloses uses of specific cholesterol sulfate salts, such as calcium, magnesium, sodium, and potassium salts, for promoting the water retention function of skin, consistent with the teachings of **Abe ‘911** (see the English translation of **Abe ‘314**, paragraph [0007]). Nothing in **Abe ‘314** teaches or suggests use of the cholesterol sulfate salts in a manner different from that taught by **Abe ‘911**.

Therefore, **Abe ‘314** does not remedy the above-described deficiency of **Abe ‘911** and **Shimada** and thus cannot support the rejection against claim 4 of the present application.

Response to §103 Rejections of Claims 6-9 and 14-15 Over Abe ‘911, Shimada, and Bernstein

Claims 6-9 and 14-15 were rejected by the Examiner in the outstanding Office Action under 35 U.S.C. §103(a) as allegedly obvious over **Abe ‘911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of International Patent Application Publication No. WO90/01323 to Bernstein (hereinafter “**Bernstein**”).

Claims 6-9 and 14-15 depend from claims 1 and 13, respectively, and therefore incorporate all the limitations recited by claims 1 and 13, including the combination of cholesterol sulfate or a salt thereof with an exfoliant or an amino sugar.

As discussed in the above section pertaining to claims 1 and 13, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe ‘911** and the exfoliant or amino sugar (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claims 1 and 13 are therefore patentably distinguished over **Abe ‘911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant or amino sugar.

Bernstein only discloses uses of fatty acids, such as arachidonic, linoleic, linolenic, palmitic, stearic, oleic and docosanoic acids, and sterols, such as cholesterol and cholesterol sulfate, for improving the protective water barrier of the stratum corneum layer of the skin and treating dry skin. Nothing in **Bernstein** teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant or amino sugar.

Therefore, **Bernstein** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejections against claims 6-9 and 14-15 of the present application.

Response to §103 Rejections of Claim 10 Over Abe '911, Shimada, and Kitada

The Examiner rejected claim 10 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of Japanese Patent Application Publication No. 10-017458 to Kitada (hereinafter "**Kitada**").

Claim 10 directly depends from claim 1 and therefore incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof with an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant. **Kitada** only discloses use of a plant extract from *Salvia officinalis* L, which contains sclareolide, for improving the uniformity of skin and preventing skin darkness caused by aging. Nothing in **Kitada** teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant.

Therefore, **Kitada** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 10 of the present application.

Response to §103 Rejections of Claim 11 Over Abe '911, Shimada, and Takahashi

The Examiner further rejected claim 11 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of Japanese Patent Application Publication No. 06-263627 to Takahashi et al. (hereinafter "**Takahashi**").

Claim 11 directly depends from claim 1 and therefore incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof with an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant. **Takahashi** only discloses use of a plant extract from white birch, which contains protease inhibitors, for preventing skin aging, improving the stratum corneum, and imparting skin-beautifying effects. Nothing in **Takahashi** teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant.

Therefore, **Takahashi** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 11 of the present application.

Response to §103 Rejections of Claim 12 Over Abe '911, Shimada, Kitada, and Takahashi

The Examiner rejected claim 12 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of **Kitada** and **Takahashi**.

Claim 12 directly depends from claim 1 and therefore incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof with an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant.

Further, as discussed hereinabove in sections pertaining to claims 10 and 11, nothing in the **Kitada** and **Takahashi** reference teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant. In other words, **Kitada** and **Takahashi** do not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 12 of the present application.

Response to §103 Rejections of Claim 20 Over Abe '911, Shimada, Bernstein, Kitada and Takahashi

The Examiner rejected claim 20 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of **Bernstein**, as applied to claims 6-9 and 14-15 above, and further in view of **Kitada** and **Takahashi**.

Claim 20 directly depends from claim 19 and therefore incorporates all the limitations recited by claim 19, including the combination of cholesterol sulfate or a salt thereof with an amino sugar.

As discussed in the above section pertaining to claim 19, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the amino sugar disclosed by **Shimada**, and claim 19 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an amino sugar.

Further, as discussed hereinabove in the section pertaining to claims 6-9 and 14-15 and the sections pertaining to claims 10 and 11, nothing in the **Bernstein**, **Kitada**, and **Shimada** references teaches or suggests combination of cholesterol sulfate or a salt thereof with an amino sugar. In other words, the secondary references **Bernstein**, **Kitada**, and **Shimada** do not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 20 of the present application.

Response to the Obviousness-Type Double Patenting Rejection

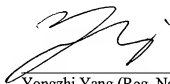
In the outstanding Office Action, the Examiner reiterated the previously raised provisional obviousness-type double patenting rejection against claims 1, 6, 8 and 9 of the present application based on claims 7-20 of U.S. Patent Application No. 10/424,616 (hereinafter "the '616 Application").

However, the '616 Application has been abandoned as of August 17, 2007 and is therefore no longer co-pending with the present application. Correspondingly, the provisional obviousness-type double-patenting rejection against claims 1, 6, 8 and 9 of the present application is moot.

Conclusion

Based on the foregoing, Applicants submit that claims 1-20 as currently pending in the present application are in condition for allowance. Accordingly, Applicants respectfully request the Examiner to issue a Notice of Allowance in favor of the Applicants.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Yongzhi Yang', is positioned above a horizontal line.

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